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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|------------------------|---------------------|------------------|
| 10/735,269  | 12/12/2003  | Robert M. Vidlund      | MYO1002US           | 3613             |
| 9561 7590 03/23/2009<br>POPOVICH, WILES & O'CONNELL, PA<br>650 THIRD AVENUE SOUTH<br>SUITE 600<br>MINNEAPOLIS, MN 55402 |             |                        |                     |                  |
| EXAMINER<br>FLICK, JASON E  |             |                        |                     |                  |
| ART UNIT<br>3763  |             | PAPER NUMBER           |                     |                  |
| MAIL DATE<br>03/23/2009   |             | DELIVERY MODE<br>PAPER |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/735,269

**Applicant(s)**

VIDLUND ET AL.

**Examiner**

JASON FLICK

**Art Unit**

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 July 2004.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-33 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-33 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 12 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4, 6-18, and 20-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Stevens et al. (patent number 5,855,614).
3. [Claims 1-4 and 15-18] Stevens teaches a method for direct localized therapeutic treatment of myocardial tissue in heart having a pathological condition comprising the steps of: identifying a target region of the myocardium (septal defect) (figure 8a); advancing an element across the septum of the heart to deliver passive material (figure 9); and applying said material directly and substantially only to at least a portion of the myocardial tissue of the target region substantially identified in step (a) to physically modify the mechanical properties of said tissue, including increasing systolic performance and not decreasing the global diastolic performance (figure 19).
4. [Claims 6-10 and 20-24] Stevens teaches the method steps of claims 1 and 15, upon which claims 6-10 and 20-24 depend. In addition, Stevens discloses a method wherein the target region at least in part underlies (ventricular septum) the papillary muscles associated with the mitral valve (column 10, lines 10-15), wherein the material applied is a device (figure 19) and comprises a polymer (column 19, lines 28-35) or a bioactive agent (column 25, lines 15-18).

5. [Claims 11-14 and 25-28] Stevens teaches the method steps of claims 1 and 15, upon which claims 11-14 and 25-28 depend. Stevens further discloses a method comprising a mini-thoracotomy (figure 8a), proceeded by the applying step including percutaneously employing a catheter to apply material intramyocardially (figure 8a, item 22).
6. [Claims 29 and 30] Stevens teaches the method steps of claim 15, upon which claims 29 and 30 depend. In addition, Stevens teaches the step of performing an additional therapeutic or diagnostic procedure (electrophysiology mapping and ablation) either before or after the applying step employing access to the heart gained during the advancing step (column 28, lines 52-56).
7. [Claims 31 and 32] Stevens teaches the method steps of claim 15, upon which claims 31 and 32 depend. In addition, Stevens teaches an advancing step comprising advancing an element across the atrial septum or the ventricular septum of the heart (column 4, lines 9-12).

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 5, 19, and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens et al. (patent number 5,855,614), in view of Linden et al. (patent number 5,634,936).

12. [Claims 5 and 19] Stevens teaches the method steps of claims 1 and 15, upon which claims 5 and 19 depend. Stevens is silent on a target region including a myocardial infarct. However, Linden teaches a similar procedure to Stevens, wherein the procedure discloses a target region including a myocardial infarct (column 1, lines 54-64). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Stevens with the method step of including a target region comprising a myocardial infarct, as taught by Linden, in order to utilize the disclosed method to treat septal perforations following myocardial infarctions.

13. [Claims 31-33] Stevens teaches the method steps of claim 15, upon which claims 31-33 depend. Although Stevens discloses advancing an element across the atrial septum or the ventricular septum (as discussed above), Stevens does not specifically disclose advancing an element across both structures during the same procedure. However, Linden teaches a similar procedure to Stevens, wherein the advancing step comprises advancing an element across both the atrial and ventricular septa of the heart (figure 4b). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method steps taught by Stevens with the method step of advancing an element across both the atrial and ventricular septa of the heart, as taught by Linden, in order to utilize the disclosed method to simultaneously treat multiple septal defects of the heart.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JASON FLICK whose telephone number is (571)270-7024. The examiner can normally be reached on Monday through Thursday, 7:00am to 5:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F./  
Examiner, Art Unit 3763  
03/16/2009

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763